§ 522.2476

pregnant mares, lactating mares, horses intended for breeding, foals, or horses with metabolically unstable conditions. The safety of TolazineTM has not been evaluated for reversing xylazine used as a preanesthetic to a general anesthetic. This drug is for use in horses only and not for use in foodproducing animals. Users with cardiovascular disease (for example, hypertension or ischemic heart disease) should take special precautions to avoid accidental exposure to this product.

Accidental spillage on the skin should be washed off immediately with soap and water. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[61 FR 25785, May 23, 1996]

§522.2476 Trenbolone acetate.

- (a) [Reserved]
- (b) Sponsors. See sponsors in \$510.600(c) of this chapter for use as in paragraph (d) of this section.
- (1) No. 021641 for use as in paragraphs (d)(1) and (d)(2) of this section.
- (2) No. 057926 for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii), (d)(1)(iii), (d)(2)(i)(A), (d)(2)(ii), and (d)(2)(iii) of this section.
- (c) $Related\ tolerances.$ See §556.739 of this chapter.
- (d) Conditions of use—(1) Steers fed in confinement for slaughter—(i) Amount. Use 126 days prior to slaughter; should be reimplanted once after 63 days.
- (A) 140 milligrams (mg) trenbolone acetate (one implant consisting of 7 pellets, each pellet containing 20 mg trenbolone acetate) per implant dose.
- (B) 140 mg trenbolone acetate (one implant consisting of 8 pellets, each of 7 pellets containing 20 milligrams trenbolone acetate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.
- (ii) *Indications for use.* For improved feed efficiency.
- (iii) Limitations. Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals.
- (2) Heifers fed in confinement for slaughter—(i) Amount. Use last 63 days prior to slaughter.

- (A) 200 mg trenbolone acetate (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate) per implant dose.
- (B) 200 mg of trenbolone acetate (one implant consisting of 11 pellets, each of 10 pellets containing 20 mg of trenbolone acetate, and 1 pellet containing 29 mg of tylosin tartrate) per implant dose.
- (ii) Indications for use. For increased rate of weight gain and improved feed efficiency.
- (iii) Limitations. Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals.

[66 FR 47961, Sept. 17, 2001]

$\S\,522.2477$ Trenbolone acetate and estradiol.

- (a) [Reserved]
- (b) *Sponsors*. See sponsors in §510.600(c) of this chapter for uses as in paragraph (d) of this section.
- (1) No. 021641 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(B), (d)(1)(ii), (d)(1)(iii), and (d)(3) of this section.
- (2) No. 057926 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(i)(D), (d)(1)(ii), (d)(1)(iii), (d)(2), (d)(3)(i)(A), (d)(3)(ii), and (d)(3)(iii) of this section.
- (c) Related tolerances. See §§ 556.240 and 556.739 of this chapter.
- (d) Conditions of use—(1) Steers fed in confinement for slaughter—(i) Amount. (A) 120 milligrams (mg) trenbolone acetate and 24 mg estradiol (one implant consisting of 6 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.
- (B) 120 mg trenbolone acetate and 24 mg estradiol (one implant consisting of 7 pellets, each of 6 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.
- (C) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose.
- (ii) *Indications for use*. For increased rate of weight gain and improved feed efficiency.
- (iii) Limitations. Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals.

Food and Drug Administration, HHS

- (D) 80 mg trenbolone acetate and 16 mg estradiol (one implant consisting of 4 pellets), or 120 mg trenbolone acetate and 24 mg estradiol (one implant consisting of 6 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.
- (2) Heifers fed in confinement for slaughter—(i) Amount. (A) 140 mg trenbolone acetate and 14 mg estradiol (one implant consisting of 7 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraphs (d)(2)(ii)(A) and (d)(2)(ii)(B) of this section.
- (B) 80 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 4 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraph (d)(2)(ii)(B) of this section.
- (C) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraph (d)(2)(ii)(A) of this section.
- (ii) *Indications for use*. (A) For increased rate of weight gain and improved feed efficiency.
 - (B) For increased rate of weight gain.
- (iii) Limitations. Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals.
- (3) Pasture cattle (slaughter, stocker, feeder steers, and heifers)—(i) Amount. (A) 40 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 2 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.
- (B) 40 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 3 pellets, each of 2 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.
- (ii) *Indications for use.* For increased rate of weight gain.
- (iii) Limitations. Implant subcutaneously in ear only. Not for use

in animals intended for subsequent breeding or in dairy animals.

[60 FR 4376, Jan. 23, 1995, as amended at 61 FR 29480, June 11, 1996; 61 FR 41499, Aug. 9, 1996; 62 FR 28629, May 27, 1997; 64 FR 42597, Aug. 5, 1999; 64 FR 48294, Sept. 3, 1999; 65 FR 10706, Feb. 29, 2000; 65 FR 26748, May 9, 2000; 65 FR 45879, July 26, 2000; 65 FR 70663, Nov. 27, 2000; 66 FR 47961, Sept. 17, 2001; 67 FR 5724, Feb. 7, 2002]

§ 522.2478 Trenbolone acetate and estradiol benzoate.

- (a) Sponsor. See 000856 in §510.600(c) of this chapter.
- (b) Related tolerance. See §§ 556.240 and 556.739 of this chapter.
 - (c) [Reserved]
- (d) Conditions of use—(1) Steers—(i) Amount. 200 milligrams of trenbolone acetate and 28 milligrams of estradiol benzoate (one implant consisting of 8 pellets, each pellet containing 25 milligrams of trenbolone acetate and 3.5 milligrams of estradiol benzoate) per animal.
- (ii) *Indications for use*. For increased rate of weight gain and improved feed efficiency in steers fed in confinement for slaughter.
- (iii) Limitations. Implant subcutaneously in ear only.
- (2) Heifers—(i) Amount. 200 milligrams of trenbolone acetate and 28 milligrams of estradiol benzoate (one implant consisting of 8 pellets, each pellet containing 25 milligrams of trenbolone acetate and 3.5 milligrams of estradiol benzoate) per animal.
- (ii) Indications for use. For increased rate of weight gain in heifers fed in confinement for slaughter.
- (iii) Limitations. Implant subcutaneously in ear only. Not for dairy or beef replacement heifers.
- [61 FR 14482, Apr. 2, 1996, as amended at 61 FR 29479, June 11, 1996; 63 FR 63789, Nov. 17, 1998; 64 FR 18573, Apr. 15, 1999]

§ 522.2483 Sterile triamcinolone acetonide suspension.

- (a) *Specifications*. Each milliliter of suspension contains 2 or 6 milligrams triamcinolone acetonide.
- (b) *Sponsor*. See 000010 and 053501 in \$510.600(c) of this chapter.